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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/662,621	09/15/2003	Michael S. Williams	9362-4	9764

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EXAMINER	
LEVY, NEIL S	

ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 09/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/662,621	WILLIAMS ET AL.	
	Examiner	Art Unit	
	NEIL LEVY	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 August 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14 and 16-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14 and 16-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 4/07; 5/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The amendment of June 23, 2005 has been entered.

The final rejection is hereby withdrawn; an updated search has resulted in the following rejections applicable :

Claims 1-14,16-26 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over BAWA et al 6071439.

Bawa provides biocompatible intraluminal prosthesis inclusive of stents (catheters & vessel substitutes- lines 19-39, col. 6) although focus is on contact lenses & is exemplified as such. Note that biomedical prostheses surfaces are stated to be of concern- polymeric coatings(instant claims 13 , 25) would thus be seen as obvious to one of ordinary skill in the art to apply, as taught within the Bawa disclosure, in order to provide a suitable in vivo prosthetic device, because Bawa states that such modifications would be evident to the artisan(lines 36-39, col. 6) .The invention is application of

supercritical carbon dioxide (SCD) to polymeric prostheses in order to remove the instant toxic materials, solvents, unpolymerized monomers, oligomers & polymerization by-products (col. 2, lines 51-56) contained therein. The instant method is seen at claims 5, immersion of the polymeric prosthesis in an enclosed chamber, & applying SCD – claim 7, with a cosolvent, propanol-claim 9 and col. 2 lines 31-36; to remove toxics-claim 13. Heat and pressure are applied (col. 2, lines 43-56). Claims 1-8,24 are seen as anticipated, as the portion of a device are treated when the device is treated.

Claims 9, 20,& 16-19 require a stent; this is seen as a species of the general description of vessel substitiutes & catheters @ col. 6, and thus clearly recognized, or at least within the scope of the artisan to treat, with the process exemplified with contact lenses. The polymers are those instantly claimed (claim 11, 14- hydrogels (lines 14- 26 , col 3) thus erodible , and acrylate polymers (col 3, lines 11-14), thus non-erodible. Instant claims 11,12,14, 16-20,22 –24 & 26 are thus within the purview of one in the art to achieve; this invention is obvious over Bawa.

Masking, instant claims 10, 21 , is also taught, as Blocking-(col 5, lines 41-58).

Claims 2-14,16-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Richard - US 2003/0044514 and Greiner –EP 0405284 in view of Hile et al '99 or Bawa- et al 6071439.

Richard [0018] coats medical devices –stents, the instant intraluminal in vivo prosthesis- with a therapeutic in a closed chamber by applying heat & pressure with SCD , followed [0019] by ejection of the SCD.These are the steps of the instant process. Nothing is evident about the attendant toxics, or cosolvents, or masking.

GREINER ,of record, Shows stents (col 2, lines 33-45) of polyproylene, polyurethane impregnated with active by immersing in super critical carbon dioxide, while controlling temperature and pressure (p. 3, col. 1) then decreasing pressure (col.3, p. 3). However, Greiner does not focus, although discloses (p.3, col. 3) – methylene chloride - alcohols on removable of toxics. HILE , of record, shows that PLGA polymers,

can be treated with super critical carbon dioxide to effect removal of solvents methylene chloride and other toxics, while Hile addresses - multiple use of polymer, as of Richard, for sustained release , including

use as intra luminal prostheses (p. 177, 1.) . Stents are not specifically mentioned, but the process of utilizing SCD to remove toxics from polymeric in vivo intra luminal devices is described. However, BAWA, (above) shows that various toxic components are present in the production & treatment of in vivo prosthetic devices , and must be removed. Removal is by immersion in SCD , with selection of the particular conditions to be used dependent upon the desired component or toxic to be removed and within the skill of the artisan to determine (col 2, lines 38-56 of Bawa).

It would have been obvious to a person of ordinary skill in the at the time the invention was made desiring to utilize stents, to use the process of Richard and/or Greiner, to treat devices with SCD , as shown by Hile to permit removal of solvent/ toxic residuals, with Bawa disclosing attendant toxics are present, & must be removed, from the polymeric in vivo devices.

All the critical elements of the instant are disclosed. The processes for

preparation of ingredient are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the form of each component in order to optimize the effect desired, depending upon the particular residual , solvent or toxic to be removed, from the particular in vivo prosthesis of interest.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected result that the use of the particular ingredients' or procedures provides any greater of different level of prior art expectation as claimed, and the use of procedures and components for the functionality for which they are known to be used is not basis for patentability.

Applicant's arguments filed 8/19/05 have been fully considered but they are not persuasive. Applicant requested a pre-appeal review, & in accord with applicant's response & request for more complete exlanation of rejection oover Greiner & Hile , an updated search disclosed additional pertinent references, considered by examiner to provide the instant inventive methods and claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NEIL LEVY whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday-Friday, 7 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, THURMAN PAGE can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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NEIL S. LEVY
PRIMARY EXAMINER